IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

BRENDA PARRISH, INDIVIDUALLY AND AS ADMINISTRATRIX OF THE ESTATE OF KYLE J. PARRISH 417 Deersville Rd. Uhrichville OH 44683 Plaintiff vs. MEDTRONIC USA, INC. c/o Corporation Service Company, Statutory Agent 50 W. Broad St, Suite 1330 Columbus, OH 43215 and MEDTRONIC, INC. c/o Corporation Service Company, Statutory Agent 50 W. Broad St, Suite 1330 Columbus, OH 43215 and HEARTWARE INTERNATIONAL INC. 500 Old Connecticut Path Framingham, MA 01701 Defendants	CASE NO. 1:19-CV-02995 JUDGE JAMES S. GWIN **FIRST AMENDED COMPLAINT** **Type: TORT; PRODUCT LIABILITY; WRONGFUL DEATH** **JURY DEMAND ENDORSED HEREON**

Now comes the Plaintiff, Brenda Parrish, Individually and as Administratrix of the Estate of Kyle J. Parrish, by and through undersigned Counsel, and for her Complaint states the following:

1. This Complaint is to be read as one harmonious document, and each paragraph of the Complaint is intended to, and does indeed incorporate the statements contained in every other paragraph of the Complaint as if fully rewritten therein.

2. This case involves a left ventricular assist device, called a HeartWare HVAD, which was implanted in Plaintiff's decedent, Kyle J. Parrish, on or a bout May 5, 2017, together with its constituent components, specifically including the controller unit, batteries, battery charging station, and AC/DC adapter. (Collectively "HVAD Device"). The HVAD Device received Premarket Approval ("PMA") from the FDA on November 20, 2012, for use as a "bridge to cardiac transplantation" for patients who were awaiting a heart transplant.

3. The HVAD Device is classified by the FDA as a medical device. It was developed, designed, manufactured, marketed, and distributed by Defendant HeartWare International, Inc., a wholly-owned subsidiary of Defendant Medtronic USA, Inc., itself a wholly-owned subsidiary of Defendant Medtronic, Inc.

4. The HVAD Device was implanted in Plaintiff's Decedent, Kyle J. Parrish, as a "destination therapy," meaning that Mr. Parrish was not intended to use the HVAD Device as a "bridge" to receiving a cardiac transplant, but would instead be reliant on the HVAD Device to supplement his left ventricular function indefinitely. Use of the HVAD Device in this manner did not have PMA by the FDA until after September 27, 2017. At the time of implantation, use of the HVAD Device as a "destination therapy" was an off-label use.

5. Despite this lack of FDA approval and the FDA's explicit concerns about the dangers to patients posed by off-label uses, the HVAD Device was improperly promoted by the Defendants to be used off-label as a "destination therapy."

6. Beginning on or about November 20, 2012, and lasting until September 27, 2017, Defendants began a campaign of persuasion through material misrepresentation of the safety of using the HVAD Device as a “destination therapy” targeted at cardiovascular surgeons implanting HVAD Devices. Plaintiff’s Decedent’s cardiovascular surgeon, Dr. Edward Soltesz, who had implanted the HVAD Device in the Decedent, was persuaded by Defendants’ consultant "Key Opinion Leaders," who were paid physician promoters, to expand their use of the HVAD Device for off-label uses including as “destination therapy.”

7. When the HVAD Device is used off-label, it can cause severe injuries to the patient, including death of the patient due to exceeding the known tolerances of the HVAD Device resulting in device failure. Specifically, prolonged use of the HVAD Device such as what is encountered in “destination therapy” results in ingress of water into the HVAD Device, causing corrosion of power connections which then results in the HVAD Device losing power. When the HVAD Device loses power, the HVAD Device ceases to supplement left ventricular function. In a patient with heart failure, such as Plaintiff’s Decedent, Kyle J. Parrish, blood would then cease to circulate and the patient would die in mere moments following the HVAD Device losing power in this manner.

8. Notwithstanding overwhelming and substantial evidence (including studies sponsored by Defendants) demonstrating these increased risks of off-label use of the HVAD Device as “destination therapy,” Defendants recklessly and/or intentionally misrepresented, minimized, downplayed, disregarded, and/or completely omitted these off-label risks while promoting the HVAD Device to

cardiovascular surgeons, including Dr. Edward Soltesz, for off-label use as "destination therapy."

9. Moreover, the actual rate of incidence of serious side effects from off-label use of the HVAD Device as "destination therapy" is, in fact, much greater than that disclosed by Defendants to Dr. Edward Soltesz and Plaintiff. With respect to the off-label use of the HVAD Device as "destination therapy," Defendants made deliberately misleading omissions of material facts when they failed to accurately disclose the significant off-label risks of which it knew or should have known.

10. Because of Defendants' wrongful conduct in actively and illegally promoting the off-label use of the HVAD Device as "destination therapy" and because of Defendants' additional wrongful conduct in minimizing, concealing, and downplaying the true risks of these non-FDA-approved, off-label uses of its product, Plaintiff's Decedent, Kyle J. Parrish, elected to underdo surgery to implant the HVAD Device as a "destination therapy" and forego lifesaving cardiac transplant.

11. Plaintiff's Decedent and his physician relied on Defendants' false and misleading statements of material fact including statements and publications by Defendants' "opinion leaders" or "thought leaders" and sales representatives. Defenadnts orchestrated a marketing campaign from at least November 20, 2012 through September 27, 2017 to persuade cardiovascular surgeons, including Dr. Edward Soltesz, to use the HVAD Device in dangerous off-label use as "destination therapy." Indeed, absent Defendants' extensive off-label promotion campaign, Dr. Edward Soltesz would never have advised Plaintiff's Decedent to forego the

HVAD Device's implantation as a bridge to cardiac transplantation and thus forego life saving cardiac transplantation.

12. As a result of Plaintiff's Decedent's off-label HVAD Device implantation as "destination therapy," Plaintiff suffered the bodily injuries, death and damages described herein.

PARTIES

12. At all times referenced herein, Plaintiff Brenda Parrish, Individually and as Administratrix of the Estate of Kyle J. Parrish, was a resident of the City of Uhrichsville, County of Tuscarawas, and the State of Ohio.

13. Plaintiff was appointed Administratrix of the Estate of Kyle J. Parrish, Deceased, by the Probate Court of Tuscarawas County, Ohio being Case Number 2018 ES 59626. The Plaintiff brings this action as personal representative for the exclusive benefit of the surviving next of kin of the Decedent, Kyle J. Parrish.

14. All named Defendants are engaged in the manufacture, marketing, sale and distribution of ventricular assist medical devices along with related accessories and services to consumers and the public at large through medical services providers, healthcare systems, surgical services providers, and/or other entities involved in the commercial market of medical devices in the State of Ohio.

15. All named Defendants are authorized to do business and are doing business in the State of Ohio, including Cuyahoga County.

16. All named Defendants sold, marketed and/or distributed the HVAD Device used by Plaintiff Kyle Parrish on or about November 27, 2017.

JURISDICTION AND VENUE

17. This court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, because there is complete diversity of citizenship between Plaintiff and the Defendants, and because Plaintiff alleges an amount in controversy in excess of $75,000, exclusive of interest and costs.

18. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of Ohio. At all relevant times the Defendants transacted, solicited, and conducted business in Ohio through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Ohio.

19. Venue is proper in this district pursuant to 28 U.S.C. § 139l(a) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 139l(c), because Defendants are all corporations that have substantial, systematic, and continuous contacts in the State of Ohio, and they are all subject to personal jurisdiction in this District.

COUNT ONE: FRAUDULENT MISREPRESENTATION

20. At all relevant times, the Defendants negligently manufactured, marketed, advertised, promoted, sold and distributed the HVAD Device as a safe and effective device to be used for “destination therapy.” Defendants negligently, recklessly, and/or intentionally promoted the HVAD Device for off-label use to cardiovascular surgeons and heart failure patients, including the Plaintiff’s Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, and downplayed to Decedent and his cardiovascular surgeon its dangerous effects, including but

not limited to the downplaying of the dangers of implanting an HVAD Device as an off-label "destination therapy" such as that performed on the Plaintiff.

21. At all relevant times, the Defendants misrepresented the safety of the HVAD Device to Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, and recklessly, willfully, and/or intentionally failed to alert Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, of the significant danger to patients resulting from the off-label use of HVAD Devices as "destination therapy."

22. Defendants and their agents knew or should have known and/or recklessly disregarded the materially incomplete, false, and misleading nature of the information that they caused to be disseminated to the Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, regarding the HVAD Device and including Defendants' surreptitious campaign to promote the product for off-label uses (i.e., uses not approved or even evaluated by the FDA). The scheme described herein could not have been perpetrated over a substantial period of time, as has occurred here, without the knowledge and complicity of personnel at the highest level of Defendants' institutions, including their corporate officers.

23. At all relevant times, Defendants knew and/or had reason to know that the HVAD Device was not safe for off-label use as "destination therapy" because the device had never been approved for use as "destination therapy."

24. At all relevant times, Defendants knew and/or had reason to know that the HVAD Device was not safe for off-label use because it had not been approved for off label use; and its safety and efficacy for off-label use was either unknown, or was known by Defendants to be unsafe and ineffective.

25. Defendants' acts to promote off-label use of the HVAD Device, their knowledge of, but failure to disclose, the growing adverse events associated with the product, Defendants' continued payments to certain cardiovascular surgeon "opinion leaders" to promote off-label uses, and FDA regulatory action against Defendants demonstrate a conscious and reckless disregard for the health and safety of heart failure patients such as Plaintiff's Decedent.

26. At all relevant times, Defendants knew and/or had reason to know that their representations and suggestions to physicians that the HVAD Device was safe and effective for off-label use were materially false and misleading and that Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, would rely on such representations.

27. Defendants knew and/or had reason to know of the likelihood of serious injuries caused by the off-label use of the HVAD Device, but they concealed this information and did not Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, preventing Decedent and his physicians from making informed choices in selecting cardiac transplant surgery.

28. The prevailing best scientific and medical knowledge, as discussed supra, demonstrated prior to the date of Plaintiff's Decedent's injury that off-label use of the HVAD Device was likely to cause the Plaintiffs' injuries as stated herein. This prevailing scientific and medical knowledge was known or knowable by Defendants for at least a year or more prior to Decedent's off-label HVAD Device surgery.

29. Defendants had knowledge and information reflecting the true risks and dangers to heart failure patients of off-label the HVAD Device, the extent of the off-label

use, and their reckless promotion of the off-label uses. Despite this knowledge, Defendants knowingly and recklessly conducted an egregious off-label promotion campaign to the detriment of Plaintiff's Decedent.

30. Defendants and their agents encouraged the off-label promotion of the HVAD Device described throughout this Complaint, notwithstanding their knowledge of the serious adverse events that patients could, and did, suffer, which has resulted in the death of patients.

31. Defendants improperly promoted and marketed the HVAD Device to Plaintiff's Decedent's implanting surgeon for off-label use as "destination therapy," and this improper promotion and marketing improperly influenced Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, in their decision to implant the HVAD Device in Decedent as "destination therapy."

32. Defendants, as herein described, directly and indirectly promoted, trained, and encouraged Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, to implant the HVAD Device as "destination therapy."

33. The Defendants recklessly and/or fraudulently promoted and marketed the HVAD device to Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, for use as a "destination therapy."

34. At all relevant times, Defendants misrepresented the safety of The HVAD Device to physicians and spine patients, including to Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz and recklessly, willfully, or intentionally failed to inform Plaintiff and Plaintiff's physicians of the significant dangers to patients resulting from the off-label use of The HVAD Device.

35. Any warnings Defendants may have issued concerning the dangers of off-label uses of The HVAD Device or regarding specific risks of those uses were insufficient or negated in light of Defendants' contradictory prior, contemporaneous, and continuing illegal promotional efforts and promotion of The HVAD Device for non FDA- approved, off-label use as "destination therapy" and contemporaneous efforts to hide or downplay the true risks and dangers of the off-label uses of The HVAD Device.

36. Plaintiff's Decedent would not have consented to be treated with the off-label use of The HVAD Device as "destination therapy" had he known of or been informed Defendants or by his cardiovascular surgeon of the true risks of the off-label use of the HVAD Device for "destination therapy."

37. Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, relied on Defendants' misrepresentations regarding the safety and efficacy of the HVAD Device in Decedent's implant surgery. Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, did not know of the specific risks and/or were misled by Defendants, who knew or should have known of the true risks but consciously chose not to inform Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, of those risks and to actively misrepresent those risks to the Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz.

38. Defendants' off-label promotion and marketing caused Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz to decide to implant The HVAD Device in Decedent as "destination therapy."

39. Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, received and relied on Defendants' improper promotion of the off-label uses, and Defendants' inadequate warnings which hid or downplayed the risks of off-label use of The HVAD Device as "destination therapy." Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz would have elected alternative treatment in the absence of Defendants' false and misleading promotion of the off-label use as "destination therapy."

40. The above-described conduct violates federal law, specifically 21 C.F.R. § 801.4 governing appropriate advertising standards for Defendants in their marketing and representations made to Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz, regarding the use, and risks of use, of the HVAD Device. The above-describe misrepresentations regarding the use of the HVAD Device as "destination therapy" are violative of 21 C.F.R. § 801.4 in that this use is not a use approved by the PMA received on November 20, 2012.

41. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venture of each of the other Defendants named herein and was at all times operating and acting within the purpose and scope of said agency, service, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

42. At all times herein mentioned, Defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted

adoption and approval of said actions and all Defendants and each of them, thereby ratified these actions.

43. There exists and, at all times herein mentioned there existed, a unity of interest in ownership between certain Defendants and other certain Defendants, such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

44. At all times herein mentioned, the Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling products for use by the Plaintiff's Decedent and his cardiovascular surgeon, Dr. Edward Soltesz. As such, each of the Defendants is individually, as well as jointly and severally, liable to Plaintiff for their damages.

45. The harm which has been caused to Plaintiff resulted from the conduct of one or various combinations of the Defendants, and through no fault of the Plaintiff. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one or which combination of the Defendants caused Plaintiff's injuries.

46. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by Plaintiff.

COUNT TWO: STRICT PRODUCT LIABILITY

47. Defendants designed and marketed The HVAD Device for implantation in patients with heart failure. The HVAD Device is designed to assist the failing left ventricle of the heart to pump blood to the body, thus sustaining the patient's life until a heart transplant can be received.

48. The current regulatory framework for medical device approval was established in the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"). The MDA contains a three-class classification system for medical devices. Class I devices pose the lowest risk of consumers' heath, do not require FDA approval for marketing, and include devices such as tongue depressors. Class II devices pose intermediate risk and often include special controls including post-market surveillance and guidance documents. Finally, Class III devices pose the greatest risk of death or complications and include most implantable surgical devices such as cardiac pacemakers, coronary artery stents, automated external defibrillators, and several types of implantable orthopedic devices for spine and hip surgery. The HVAD Device is a Class III device.

49. Manufacturers such as the Defendants seeking to market Class III devices, such as The HVAD Device, are required to submit a Premarket Approval Application ("PMA") that must be evaluated and approved by the FDA. The PMA requires the manufacturer to demonstrate the product's safety and efficacy to the FDA through a process that analyzes clinical and other data, including (1) technical

data and information on the product, including non-clinical laboratory studies and clinical investigations; (2) non-clinical laboratory studies that provide information on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests of the device- all of which must be conducted in compliance with federal regulations which set forth, inter alia, criteria for researcher qualifications, facility standards and testing procedures; and (3) clinical investigations in which study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, results of statistical analyses, and any other information from the clinical investigations are provided, including the results of any investigation conducted under an Investigational Device Exemption ("IDE").

50. A PMA requires that all pertinent information about the device be articulated in the application and requires the manufacturer to specify that medical device's "intended use." The indications for use required on the label are based on the nonclinical and clinical studies described in the PMA. Indications for use for a device include a general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for whom the device is intended.

51. In addition, each PMA submission must include copies of all proposed labeling for the device, which must comply with federal requirements. Specifically, the label must include the common name of the device, quantity of contents, the name and address of the manufacturer, as well as any prescription use restrictions, information for use (including indications, effects, routes, methods,

frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions), instructions for installation and operation, and any other information, literature, or advertising that constitutes "labeling" under the FDCA. Approval of the product's labeling is conditioned on the applicant incorporating any labeling changes exactly as directed by the FDA. A copy of the final labeling must be submitted to the FDA before marketing.

52. Additionally, the HVAD Device must conform to Good Manufacturing Practices ("GMP") as provided in the PMA. The November 20, 2012 PMA specifically incorporates the Summary of Safety and Effectiveness Data ("SSED") for the HVAD Device, which states that the HVAD Device must meet the industry standards for electrical safety delineated in IEC-60601-1.

53. Additionally, the industry standards for electrical safety delineated in IEC-60601-1 have been specifically recognized by the FDA to apply to all Class III medical devices, including the HVAD Device, as of April 4, 2016.

54. Amongst other guidelines, IEC-60601-1 provides that electrical power supply connections in medical devices must be protected from developing a hazardous condition due to the ingress of water or other fluids.

55. A foreseeable risk of harm from failing to meet the above industry standard included the sudden loss of power of the HVAD Device, resulting in serious harm and/or death to persons such as Plaintiff's Decedent.

56. All named Defendants acting by and through their authorized agents, employees and servants, were negligent and/or careless in the manufacture of the HVAD Device implanted in Plaintiff's Decedent in that the HVAD Device was not sufficiently protected against the ingress of water into the electrical power supply

connections of the device, as required by the IEC-60601-1 industry standards incorporated in the HVAD Device PMA through the SSED and the FDA's recognition of this industry standard as a good manufacturing practice. This condition of the HVAD Device was unreasonably and inherently dangerous to the Decedent's health and safety which existed at the time the Products left the hands of these Defendants until it caused injury and harm to Plaintiff.

57. The HVAD Device manufactured and/or distributed by these Defendants, their agents, servants and/or employees was defective in manufacture as described above such that when the HVAD Device left the hands and control of these Defendants, it deviated materially from the above industry performance standards, and/or differed from otherwise identical units manufactured to the same design formula and/or specifications. The unreasonably and inherently dangerous condition of the HVAD Device carried a foreseeable risk of harm i.e., malfunctioning and/or catastrophic loss of power supply of these Defendants' aforementioned HVAD Devices associated with the design and/or formulation, exceeded its benefits. The HVAD Device was thus more dangerous than an ordinary and reasonably prudent consumer would expect when used in its reasonably foreseeable manner.

58. As a direct and proximate result of the tortious conduct of all Defendants, their agents, servants and/or employees violated ORC §2307.72 through §2307.80.

59. As a direct and proximate result of the defective condition of HVAD Device which was manufactured, designed, tested, modified, marketed and/or distributed by these Defendants, and the tortious conduct of these Defendants, Plaintiff sustained serious personal injuries, emotional distress, psychological injuries,

distress, economic losses, medical expenses, disability, expense, non-economic damages, economic losses, permanent and fatal injuries, conscious pain and suffering, along with mental anguish from the time of the negligence until present.

60. That as a direct and proximate result of the joint, combined, and concurrent negligence, recklessness, willful and wanton conduct of the Defendants, their agents, servants and employees, the Decedent, Kyle J. Parrish died on November 27, 2017. Kyle J. Parrish is survived by Brenda Parrish and other next of kin, all whom are beneficiaries of this action.

61. The beneficiaries and next of kin of Kyle J. Parrish have suffered damages for the loss of services for the time that he was expected to live.

62. The beneficiaries of Kyle J. Parrish have suffered damages for the loss of society over his life expectancy, including the loss of companionship, care, assistance, attention, advice, counsel, guidance, comfort, society, and consortium.

63. The beneficiaries and next of kin of Kyle J. Parrish have suffered damages for the mental anguish caused by his death and his pain and suffering.

64. The beneficiaries and next of kin of Kyle J. Parrish have suffered damages which are otherwise recoverable under O.R.C. 2125.02.

65. That the Estate of Kyle J. Parrish has incurred reasonable funeral and burial expenses.

THIRD COUNT: PUNITIVE DAMAGES

66. The above referenced acts of Defendants, their agents, servants and/or employees were willful and malicious, in that these Defendants' conduct was carried on with a conscious, reckless and/or flagrant disregard for the safety and rights of the Plaintiff. The unconscionable conduct of these Defendants, their

agents, servants and/or employees thereby warrants assessment of exemplary and punitive damages.

67. The conduct of these Defendants, their agents, servants and/or employees was flagrant, willful, wanton, malicious and reckless; and these Defendants' conduct was carried on with the conscious and flagrant disregard of the risk of serious injury or damages to the consumer and/or patient; the risk of serious bodily injury, and therefore warrants punitive damages.

WHEREFORE, Plaintiff prays for judgment against the above-named Defendants, agents, servants and/or employees jointly and severally, in an amount in excess of Seventy-five Thousand Dollars ($75,000.00), together with interest, costs, expenses, and any other relief that this Court deems proper and that justice requires.

Respectfully submitted,

PERANTINIDES & NOLAN CO., L.P.A.

/s/ Matthew A. Mooney

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JURY DEMAND

Plaintiff herein hereby demands a trial by jury on all issues contained in Plaintiff's Complaint.

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